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Filed : November 27, 2001

### REMARKS

Claims 1-28 and 61-73 are currently pending in the instant application. Claims 1-4, 7, 9-11, 13-28 and 61-73 are currently presented for examination. Claims 1, 2, 16 and 20 are currently amended. Claims 61-73 are newly added. Claims 5, 6, 8, 12 have been withdrawn from consideration by the Examiner. Applicants understand that upon allowance of a generic claim, claims to non-elected species will be given further consideration, as provided under M.P.E.P. §809.02(c). Claims 29-60 have been canceled without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of any and/or all of the canceled claims in one or more continuing applications.

Claims 1, 2, 16 and 20 have been amended. Support for the amendment of claim 1 can be found at page 22, line 26 to page 23, line 30, Figures 15A-D, original claim 20 and elsewhere throughout the specification. Claim 20 has been amended to delete a limitation that has been incorporated into claim 1. Claim 2, which depends from claim 1, has been rephrased in view of the amendment to claim 1. Claim 16 has been amended to correct its dependency.

New claims 61-73 are supported by the claims as originally filed. In particular, claims 61 and 69 correspond to claims which the Examiner indicated would be allowable if rewritten in independent form. Claims 62-68 and 70-73 depend from claims 61 and 69, respectively, and correspond to dependent claims previously presented in the instant claim set. Accordingly, no new matter has been added to the instant application.

#### Rejection of Claims 1, 7, 10, 11, 13, 17, 18, 22, and 23 Under 35 U.S.C. § 103(a)

The Examiner rejects claims 1, 7, 10, 11, 13, 17, 18, 22, and 23 under 35 U.S.C. 103(a) as being unpatentable over Nilsen *et al.* (US Patent No. 5,484,904, published on January 16, 1996) in view of Van Ness *et al.* (US Patent No. 5,106,730, published on April 21, 1992). In particular, the Examiner alleges that Nilsen *et al.* teach mixing capture beads, each having at least one transport probe affixed thereto, reporter beads, each having at least one signal probe affixed thereto, and a biological sample, under binding conditions so as to permit formation of a dual bead complex if the target agent is present in the sample, the reporter bead and capture bead each being bound to the target agent; isolating the dual bead complex from the mixture to obtain an isolate; exposing the isolate to a capture field on a support, the capture field having a capture

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agent that binds to the dual bead complex; and detecting the presence of the dual bead complex to indicate that the target agent is present in the sample. The Examiner further asserts that Van Ness *et al.* teach that a capture oligonucleotide (i.e., a capture field) is on a disc (i.e., nytran discs). The Examiner then concludes that it would have been obvious to one of ordinary skill in the art to have performed the method recited in claim 1 in view of the patents of Nilsen *et al.*, and Van Ness *et al.*.

Applicants respectfully disagree and maintain that claims 1, 7, 10, 11, 13, 17, 18, 22, and 23 are non-obvious in view of Nilsen *et al.* and Van Ness *et al.*. However, in order to expedite the allowance of the instant application, Applicants have amended claim 1 to recite the limitation that the dual bead complex is exposed to a capture field on a disc "by rotating the disc so as to move the dual bead complex to the capture field." Applicants respectfully submit that amended claim 1 is allowable because neither Nilsen *et al.* nor Van Ness *et al.* describe the step of rotating the disc so as to expose a dual bead complex to a capture zone. In particular, as acknowledged by the Examiner, Nilsen does not disclose or suggest the use of discs. The disc disclosed by Van Ness *et al.* is a nytran filter disc, commonly used for colony and plaque lifts. Van Ness *et al.* simply describe incubation of the disc with a nucleic acid-containing solution. Van Ness *et al.* do not disclose or suggest rotation of the disc so as to expose the nucleic acid to a capture field. As such, the combination of Nilsen and Van Ness does not describe all the elements of amended claim 1. Because claims 7, 10, 11, 13, 17, 18, 22, and 23 depend from newly amended claim 1, the combination of Nilsen *et al.* with Van Ness *et al.* does not render any of these claims obvious.

In view of the foregoing amendments and remarks, Applicants respectfully request that the Examiner withdraw the rejection of claims 7, 10, 11, 13, 17, 18, 22, and 23 under 35 U.S.C. § 103(a).

Rejection of Claims 9, 15 and 16 Under 35 U.S.C. § 103(a)

The Examiner rejects claims 9, 15, and 16 under 35 U.S.C. 103(a) as being unpatentable over Nilsen *et al.*, in view of Van Ness *et al.*, as applied to claims 1, 7, 10, 11, 13, 17, 18, 22, and 23 above, further in view of Mirkin *et al.* (US Patent No. 6,506,564 B1, filed on June 26, 2000). In particular, the Examiner asserts that Mirkin *et al.*, teach that one of the beads in a

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hybridization assay is fluorescently labeled and is used for detecting hybridization. The Examiner then concludes that it would have been obvious to perform the method recited in Claims 9 and 15 using fluorescent beads in view of Nilsen *et al.*, Van Ness *et al.*, and Mirkin *et al.*

Applicants respectfully disagree and maintain that Claims 9, 15 and 16 are not obvious over Nilsen *et al.*, Van Ness *et al.*, and in view of Mirkin *et al.*. However, as described above, Applicants have amended claim 1 from which claims 9, 15 and 16 depend. Mirkin *et al.* do not describe or suggest “exposing the dual bead complex to a capture field on a disc by rotating the disc so as to move the dual bead complex to the capture field.” As such, the combination of Nilsen *et al.*, Van Ness *et al.*, and Mirkin *et al.* does not describe each of the limitations of claims 9, 15 or 16, and thus, does not render any of these claims obvious.

In view of the foregoing amendments and remarks, Applicants respectfully request that the Examiner withdraw the rejection of claims 9, 15 and 16 under 35 U.S.C. § 103(a).

Rejection of Claim 14 Under 35 U.S.C. § 103(a)

The Examiner rejects claim 14 under 35 U.S.C. 103(a) as being unpatentable over Nilsen *et al.*, in view of Van Ness *et al.*, as applied to claims 1, 7, 10, 11, 13, 17, 18, 22, and 23 above, further in view of Mirkin *et al.*. In particular, the Examiner asserts that Mirkin *et al.* teach beads that can be made by different material such as latex or gold. The Examiner then alleges that it would have been obvious to one of skill in the art to perform the method of claim 14 using latex or gold reporter beads in view of Nilsen *et al.*, Van Ness *et al.*, and Mirkin *et al.*.

Applicants respectfully disagree and maintain that claim 14 is not obvious over Nilsen *et al.*, Van Ness *et al.*, and in view of Mirkin *et al.*. However, as described above, Applicants have amended claim 1 from which claim 14 depends. As stated previous, Mirkin *et al.* do not describe or suggest “exposing the dual bead complex to a capture field on a disc by rotating the disc so as to move the dual bead complex to the capture field.” As such, the combination of Nilsen *et al.*, Van Ness *et al.* and Mirkin *et al.* does not describe all of the limitations of claim 14, and thus, does not render this claim obvious.

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In view of the foregoing amendments and remarks, Applicants respectfully submit that claim 14 is not obvious and request that the Examiner withdraw the rejection of claim 14 under 35 U.S.C. § 103(a).

Rejection of Claim 21 Under 35 U.S.C. § 103(a)

The Examiner rejects claim 21 under 35 U.S.C. 103(a) as being unpatentable over Nilsen *et al.*, in view of Van Ness *et al.*, as applied to claims 1, 7, 10, 11, 13, 17, 18, 22, and 23 above, further in view of Hornes *et al.* (US Patent No. 5,512,439, published on April 30, 1996). In particular, the Examiner alleges that Hornes *et al.* disclose that different functional groups such as an amino group can be used to attach an oligonucleotide to a bead. In view of the alleged disclosure, the Examiner concludes that it would have been obvious to one of skill in the art to perform the method recited in claim 21 using an amino group to affix the capture agent to the capture layer in view of Nilsen *et al.*, Van Ness *et al.* and Hornes *et al.*

Applicants respectfully disagree and maintain that claim 21 is non-obvious in view of the patents of Nilsen *et al.*, Van Ness *et al.* and Hornes *et al.* However, as described above, Applicants have amended claim 1 from which claim 21 depends. Hornes *et al.* do not describe or suggest "exposing the dual bead complex to a capture field on a disc by rotating the disc so as to move the dual bead complex to the capture field." As such, the combination of Nilsen *et al.*, Van Ness *et al.* and Hornes *et al.* does not describe all of the limitations of claim 21, and does not render this claim obvious.

In view of the foregoing amendments and remarks, Applicants respectfully submit that claim 21 is not obvious and request that the Examiner withdraw the rejection of claim 21 under 35 U.S.C. § 103(a).

Obviousness-Type Double Patenting Rejection of Claim 1

The Examiner provisionally rejects claim 1 of the instant application over Claim 1 of copending Application No. 10/087,549 under the judicially created doctrine of obviousness-type double patenting. In particular, the Examiner asserts that claim 1 in copending Application No. 10/087,549 is directed to the same subject matter and falls entirely within the scope of claim of the instant application.

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Applicants do not concede that the claims in either application are obvious over one another. Applicants note that no claims have issued in this case or in co-pending Application No. 10/087,549. The language of pending claims in one or both applications may change before the issuance of any claim. As such, whether a terminal disclaimer is necessary cannot be determined until the issuance of at least one set of claims.

#### Objection to Claims 2-4, 19, 20 and 24-28

The Examiner objects to Claims 2-4, 19, 20 and 24-28 as being dependent upon a rejected base claim but states that these claims would be allowable if written in independent form.

Applicants have rewritten claim 2 as independent claim 61. Claim 61 incorporates all of the limitations of claim 2 and claim 1 prior to the current amendment. Claims 62 and 63, which correspond to claims 3 and 4, depend from claim 61. Furthermore, dependent claims 64-68 have been added. Applicants have also rewritten claim 24 as independent claim 69. Claim 69 incorporates all of the limitations of claim 24 and claim 1 prior to the current amendment. Claims 70-74, which correspond to claims 25-28, depend from claim 69.

In view of the foregoing remarks, Applicants respectfully submit that new claims 61-73 are allowable.

#### **CONCLUSION**

Applicants believe that all of the objections and grounds for claim rejections set forth in the aforementioned Office Action have been overcome in view of the Amendments to the Claims and Remarks set forth above. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is invited to contact the undersigned at the telephone number provided below in order to expedite the resolution of such issues.

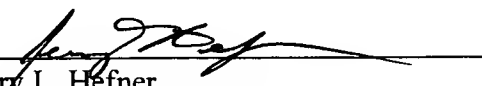
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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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